

Know Labs, Inc.
First Quarter 2024 Earnings
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Presenters

Jordyn Hujar, Chief of Staff

Ron Erickson, Chief Executive Officer

Pete Conley, Chief Financial Officer

Operator

Greetings, and welcome to the Know Labs First Quarter 2024 Earnings Conference Call. Please note, this conference call is being recorded. You may submit questions through the Q&A box on the webcast at any time.

I will now turn the conference over to Jordyn Hujar, Know Lab' Chief of Staff. Thank you, Jordyn. You may begin.

Jordyn Hujar

Thank you, Operator. Thank you, everyone, for joining us for today's conference call to review Know Labs first quarter 2024 financial results and operating highlights.

If you have not seen today's financial results, press release and 10-Q filings, please visit the Investors page on the company's website at www.knowlabs.co.

Before turning the call over to Ron Erickson, Know Labs Chairman and Chief Executive Officer, I would like to remind you that during this conference call, the company will make projections and forward-looking statements regarding future events. Any statements that are not historical facts are forward-looking statements.

We encourage you to review the company's SEC filings, including, without limitation, the company's Forms 10-K and 10-Qs, which identify specific risk factors that may cause actual results or events to differ, materially, from those described in these forward-looking statements.

These factors may include, without limitation, risks inherent in the development and/or commercialization of potential diagnostic products, uncertainty in the results of clinical trials or regulatory approvals, the need to obtain third-party reimbursement for patients' use of any diagnostic products the company commercializes, our need and ability to obtain future capital and maintenance of IP rights, risks inherent in strategic transactions such as failure to realize anticipated benefits, legal, regulatory or political changes in the applicable jurisdictions, accounting and quality controls, greater than estimated allocations of resources to develop and

commercialize technologies or failure to maintain any laboratory accreditation or FDA certification.

Therefore, actual outcomes and results may differ, materially, from what is expressed or implied by these forward-looking statements. Know Labs expressly disclaims any intent or obligation to update these forward-looking statements, except as otherwise may be required under applicable laws.

A Q&A session will follow this call. Your questions can be submitted through the webcast portal, which can be accessed through our website. We will not be taking questions over the phone during today's call.

With that, I'll turn the call over to Ron Erickson, Know Labs' CEO. Ron.

Ron Erickson

Thanks, Jordyn. Welcome, everyone, to our conference call to review the financial results and operating highlights of our first quarter for fiscal year 2024. And as you all know, our calendar year, our fiscal year ends September 30, so this is that last quarter of 2023.

Joining me today is Pete Conley, our Chief Financial Officer and Senior Vice President of Intellectual Property who will discuss our financial results.

Over the past eight months, since the announcement of our Generation 1 prototype, the Know Labs team has undertaken an accelerated work program. The results of this work will soon become public.

As we recently announced, we will be participating in the seventeenth International Conference on Advanced Technologies and Treatment for Diabetes--it's called ATTD--in Florence, Italy, from March 6 to 9. As we expect a number of material events to occur throughout this next month as we lead up to the ATTD conference, this call today will be relatively short.

I will focus, today, on providing a brief update on our progress against the four core work streams we've articulated in our previous earnings calls.

Work stream one, hardware. A critical work stream in an area with a lot of progress has been hardware development. In June, 2023, we announced the completion of our portable Gen 1 prototype device for non-invasive glucose monitoring. We spent the next several months with this device undergoing sensor characterization to better understand how our sensor performs in a completely wireless unit and answer questions surrounding battery life, signal quality, and temperature.

These tests included both testing in our lab and outside our lab with humans. Data collected throughout these tests were compared to a continuous glucose monitor, allowing us to better understand how our sensor performs in a real life setting.

Pulling from these findings, our product team, alongside our hardware firmware, electrical engineering, and industrial design partners, continue to further miniaturize the Generation 1 prototype, which will find form in the next iteration of our device. We look forward to sharing those details with you very soon.

Work Stream Two, clinical trials and data collection. Clinical testing continues to be an important area of development for the company. During the first quarter of 2024, we continued our internal trial with up to 100 participants focused on a population with diabetes and pre-diabetes. This trial has been critical in enabling the R&D team to collect more data in the hyper and hypoglycemic ranges. This trial is still ongoing.

A core focus of our next series of trials will be enrolling in more diversified population, including people with Type 1 and Type 2 diabetes. This is necessary to collect more data in the hypoglycemic range of 50 to 100 mg per deciliter, and the hyperglycemic range above 350 milliliters per deciliter, ranges that the FDA is focused on. This increase in data will be used to further refine and inform our algorithm development, another core work stream.

Work Stream Three, algorithm development. We leverage all of the data that is collected during our sensor characterization work in vitro tests and clinical trials for algorithm development. As we continue refining the algorithm, we learn exactly what data is needed to increase accuracy.

This includes a wider range of glycemic levels, along with data from a more diverse population and data that takes into account temperature, location on the body and other interferences.

Our goal is to achieve an algorithm with a mean absolute relative difference, or MARD, of 10% or less. We'll also need to meet FDA's requirements for accuracy in varying glycemic ranges, all of which we're considering during our algorithm development.

The goal of our data science and algorithm development efforts in 2024 are to further refine our algorithm to become more generalizable. We're still in the early stages of generalizable algorithm development, capable of delivering highly accurate readings to any individual in the world.

The current version of our algorithm performs well within a known population and trial. We are first focused on improving accuracy for a known population set in a different setting or trial, so we can then move into generalizability.

As we move forward, new approaches such as device calibration, will be tested to enable our development of a generalizable algorithm.

Work Stream Four, intellectual property. With respect to intellectual property, we continue to grow our portfolio. As of December 31, 2023, we have 264 patents issued, pending and in process, reflecting our continuing high rate of innovation.

These issued and pending patents cover fundamental aspects of our radio frequency spectroscopy technology and a number of unique applications. Intellectual property will continue to be a focus for the company in 2024, and as we continue to build and reinforce what we call a defensible intellectual property moat, around our technology.

As we indicated during our last earnings call, we added three new members to the Board of Directors and three new members to our medical and scientific advisory board in the last quarter. Their insights will help us build upon the existing knowledge and skills of our team in each of our four core work streams.

Finally, as I already mentioned, we'll be presenting at the Seventeenth International Conference on Advanced Technologies and Treatments for Diabetes in Florence, Italy, in early March. We'll share updates on the latest developments of our non-invasive glucose monitor there and present results from our ongoing clinical research with two abstracts accepted for e-poster presentation in the scientific program.

As we indicated in an earlier press release January 23, which I'm sure many of you saw, that presentation will be done by Dr. Virend Somers of the Mayo Clinic, who has served as both an author and a co-investigator in our current clinical research protocol. So we're very excited about that and about his presentation.

Attending and presenting at ATTD is a really important step for us in building awareness and growing our network in the medical and technical communities and those people, globally, who suffer from the pandemic of diabetes.

I'm really proud of what we've been doing, proud of what we've achieved during the last quarter. You'll start to see some results as things come to fruition, over the next several weeks. You'll see the results of our team's intense work and dedication as we disclose some of these achievements.

Now, I'd like to turn the call over to Pete Conley, so he can review our financials. Pete.

Pete Conley

Thanks, Ron. We detailed the financial results in today's first quarter of FY 2024 earnings release which, as noted by Jordyn, you can find on our website. But I'll share a few key line items.

For Q1 fiscal '24, Know Labs reported a net loss of \$3.45 million, compared to a net loss of \$3.82 million in Q1 fiscal '23, a reduction in net loss of 9.8%. This translates to earnings per

share of a loss of \$0.04, better than prior year EPS of \$0.08, an improvement of 50%, before preferred stock dividends.

In Q1 fiscal '24, we also recorded a non-cash charge to earnings of \$792,000, principally related to stock-based compensation of \$699,000.

Research and development expense for Q1 fiscal '24 was \$1.48 million, as compared to \$1.74 million in Q1 fiscal '23, a decrease of 14.7%, year-over-year. The decrease in R&D expense was related to decreased personnel and the use of external consultants to reduce the cost of product development.

Selling, general and administrative expenses for Q1 '24 were \$2.01 million, which was higher by \$106,000 than the \$1.91 million in the year ago period, an increase of 5.6%. The increase in SG&A was related primarily to an increase in salaries, reflecting key new hires, principally led by our new Head of Data Science.

Turning now to the balance sheet. As of December 31, 2023, we had cash and cash equivalents of \$4.82 million, as compared to \$8.02 million at the end of September 30, 2023. Net cash used in operations for Q1 fiscal '24 was \$3.39 million, compared to \$2.92 million in Q1 fiscal '23.

During the year ended September 30, 2023, the company made adjustments to its fixed expenses and the impact of those adjustments has, significantly, reduced our core monthly burn rate. Given the significant reduction in core fixed expenses, the company believes that it has enough cash and flexibility with its operating expenses to operate until at least June 30, 2024.

As we have stated in our Q1 fiscal '24 10-Q, we expect to raise additional funds through the issuance of equity, preferred stock and convertible debentures. To that end, we filed an \$18 million S-3 shelf registration statement on December 22, 2023, which was subsequently declared effective on January 11, 2024.

Finally, shareholder equity for Q1 fiscal '24 was \$1.23 million versus \$3.74 million in fiscal '23, ending September 30, 2023.

That concludes my review of our financial highlights and I'll return the call back to Ron for closing remarks.

Ron Erickson

Thanks, Pete. We'll now dedicate the next 10 to 15 minutes to questions submitted through the webcast portal, and first, I'd like to say thanks. We've got a number of questions that have popped up here. Pete, just following up on what you've talked about finances, there are a couple of questions that relate to finances and relate to our Q just filed.

In particular, there's a question with regards to our burn which, of course, we worked hard on reducing, but it looked like we had some increased spend in Q1, and that relates to capital and what we expect to do in terms of capital. Could you address, Pete, the question with regards to the burn last quarter and any anomalous or unusual expenditures and our capital plans, please?

Pete Conley

The way to think about our burn, there's a core burn which reflects core OpEx. Core OpEx would be salaries paid to the team, rent, insurance, auditors, etc. The core burn rate has remained relatively flat at between 700,000 and 800,000 a month. Incremental to the core burn rate are initiatives related to product development, and there we increase the pace of the Gen 2 product development. We'll talk more about that, shortly. And that entails working with our strategic partners and vendors.

So, that incremental spend on top of the core burns has been running about 200 to 300 a month, depending. One thing that impacted Q1, that was in the category of a one-time expense was we closed our last follow on financing on September 29, 2023, and then paid out a significant sum close to \$1 million to auditors and counsel to affect the documents and registration of the securities.

Ron Erickson

Thanks, Pete. Let's look at some of the other questions, here.

We've got several questions that relate to one of the things we've talked about historically, which are joint development agreements. People know that's one of the things we've been working on. People want know, any information on joint development agreements.

I think the first thing I'd say about that, it wouldn't surprise you that each one of these undertakings involves non-disclosure agreements, and those non-disclosure agreements impact what we can say, when we can say it. What I'd like to reiterate is that we are moving forward with regards to several joint development agreements.

We think that those are key critical to the future success of the company. And as a consequence, they are one of our core work streams. I'm not able to go in any particular detail, but for having an NDA with one or two of you, and we could go, we could do a deeper dive, but absent that, we are really constrained with regards to what we can say about this.

There's a question here from one of our long-term shareholders. Can you comment on the competitive landscape development over the past few years?

It's interesting. We pay a lot of attention to the competitive landscape. And one of the things I'd say about that is, if you--if we indicated we have a considerable number of patents pending issued and in the pipe, we had third-party analytics performed for us. And I think a lot of this information exists on one of the PowerPoint presentations on the Investor page of our website.

Third-party analytics performed on our IP and the IP of competitors indicate that we are the leading holder in the world, we're the number one holder in the world when it comes to intellectual property relating to non-invasive continuous glucose monitoring. We continue to do that. While we do that, we look at what other people are doing.

We look at that, sometimes, the public claims they're making which, quite candidly, are not supported by what we see behind the curtain in terms of their IP, in terms of what they're doing.

I think the thing I'll say about this is that it's a very competitive marketplace. We see the competition quite candidly is including leading incumbents like Dexcom and Abbott Labs and Medtronic. They're all competitors, because they have solutions. We don't think they're the optimal solution, but they have solutions, so they're competitors.

And they're these new entrants, which may claim to have a continuous glucose monitor. So, we pay very close attention to this. It's a competitive landscape. We think we've got a leg up, but at the end of the day, we have to be ever diligent in paying attention to this. Just know, we're alert to it.

There's a question here, will we show the second generation device in Italy?

We've sort of spoken, euphemistically, about that in our press release in January when I said that the company will share updates on the latest developments of its non-invasive blood glucose monitor. I think you're going to expect that we'll be showing updates. The form that takes all remains to be seen.

There is a question about plans to develop revenues in 2024. Pete, do you want to speak to our thoughts about revenues in 2024?

Pete Conley

Sure, Ron. I think it's clear our core focus is to take our current product family, soon to be revealed second generation. You take us through the FDA path and clearance in the United States. What we've become increasingly aware of, largely through market pull, is that there's a rest of the world opportunity that represents a revenue path for us that doesn't require the FDA.

And so, we are actively and aggressively exploring that path to see if, in fact, we can generate revenue, without having to go through the FDA. And I can't speak further to that currently, but it's something we're working on very hard.

Ron Erickson

I would say, that's something that really kind of came naturally from people taking a look at the Generation 1 product and knowing, given its size and all the rest, that it wasn't a wearable continuous glucose monitor, but it perhaps had utility for doing spot checking in places where there's a very high incidence of diabetes and a need for screening, especially in aspects of a less developed world.

I think there's another leg of the stool here that comes up to whether or not it will lead to revenue in 2024, all remains to be seen. It's really a function of resource allocation. And that is, as you all know, we have a core focus on developing a continuous non-invasive blood glucose monitor. That's happening with a technology that so many of you know is a platform technology. It's a technology that has the capacity to do other things.

One of the things that, as we have time and as we have cycles and focus here internally we think about, are there field of use licenses outside of the medical diagnostic arena where our platform technology can have utility? Is there some low hanging fruit out there? Are there some pain points that are outside the medical diagnostic arena where our platform technology could be licensed to a third-party?

That would certainly be a revenue generator. It's something that we give some time and attention to. Whether or not that can come to fruition in '24 certainly remains to be seen.

I wouldn't count on it, candidly. But I think it's the kind of thing that comes up. It comes up in conversation with shareholders with some regularity, and I want you to know it's something we're certainly alert to and as we have cycles, pay attention to.

I think I have just--we've--it looks to me like we've covered, as it wouldn't surprise you, we've had a about 20 plus people ask questions, and a number of the questions are duplicates. I think we've covered the primary categories here.

I think, well, let me add a couple things because these are just. So, we're going to ATTD, a big conference. And one of the questions, well, why would you go to a conference in Europe? Well, candidly, it's a global conference. And key opinion leaders, KOLs in the trade are going to be in Florence at this conference.

And so, we have the opportunity to meet them, to talk with them about what they're doing. We're, by the way, hosting a luncheon with a global organization called Children with Diabetes. And there'll be a number of key opinion leaders at that event. So, it's an opportunity for us to meet people, to network and to showcase what we're doing.

So, we're going to make these two presentations. They'll be made by Dr. Somers, as I indicated from Mayo Clinic. We're going to be able to present the technology, talk about what we're doing, talk about our clinical results, so it's a global conference and a great opportunity for us.

So we're excited about that. Obviously, there will be some material announcements we hope that come out of that.

I think with that, I want to thank everyone. Thanks for your questions. It's great to have engagement. I speak to a lot of you, Pete Conley speaks to a lot of you. We like keeping in touch, and so don't hesitate to reach out to us with any questions. Obviously, constrained by insider information, NDAs and all of those kinds of things, you all understand so well. But thank you for your support. Thank you for your engagement and please be in touch.

Pete Conley

Thanks so much and all the very best to you.

Jordyn Hujar

Thanks, Ron. The conference call replay will be available on our website in the coming days. Thanks for your participation.

Ron Erickson

One more thing. I can't let it go without saying Happy Valentine's Day because, in fact, that is what it is today. Happy Valentine's Day. All the very best to all of you.